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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,916	03/23/2007	Mitsuru Maeda	47234-5004-00 (219778)	1465

55694 7590 05/12/2009

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
05/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,916	MAEDA ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/05,5/6/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Claims 1-9 in the reply filed on 2/11/2009 is acknowledged. The traversal is on the ground(s) that “all claims share at least two special technical features – both the "ascorbic acid" element and the "koji" element. Accordingly all claims share at least two special technical features.” (p. 2, Remarks) This is not found persuasive because prior to Applicants’ amendment to the claim, the agent of claim 10 only stated that koji mold was present; there was no indication that 2-O-Beta-D glucopyranosyl ascorbic acid was present in the composition as stated in the Restriction Requirement. As amended, the new method claim now requires the composition of claim 1. However, as clearly evident below, the composition is obvious and hence renders the technical feature of the claims ‘non-special.’ In other words, the technical feature which links the claims must be a ‘special’ technical feature; 'novel and unobvious' in order to prevent restriction between the Inventions. Since the technical feature is not considered 'special' due to the obviousness of the claimed invention; claim 10, or 'Group II" is properly restrictable under 371 Rules.

Group II, consisting of claim 10 is now, as newly amended, a method claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise

proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

*This reference is cited merely to relay an inherent/intrinsic property and is not used in the basis for rejection *per se*.

Specification

The disclosure is objected to because of the following informalities:

It is unclear, amongst the two Abstracts which were submitted on 12/22/2005, which Abstract Applicants intend for their patent application to include. One Abstract is the abstract appearing on the published PCT document from which this case is the National Stage application; the other is a typed Abstract document containing a picture

of the compound of formula I as found in claim 1. Applicant is asked to please inform the Examiner which Abstract Applicants identify as their Abstract in this application.

The use of the trademarks Pancellase BR, Biozyme A, Intersil ODS-3, Cellulosin T2, Onozuka RS, Onozuka FA, Sugar SH1011, Marathon WBA, and Milli-Q have been noted in this application. They, as well as any other trademarks that the Examiner may have inadvertently overlooked should be capitalized wherever they appear and be accompanied by their generic terminologies.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7 state, respectively: 'wherein the koji mold is a mold belonging to the genus Aspergillus' and 'wherein the koji mold is a mold belonging to Aspergillus oryzae….'. These statements lack clear antecedent basis, leading to confusion for the following reason: Claims 6 and 7 are each dependent upon claim 1 which states 'koji mold or a processed koji.' 'Processed koji' is taken to mean 'processed koji mold' even though Applicants do not expressly state 'processed koji mold' because koji is the same as 'koji mold.' Thus, in claims 6 and 7, it is not absolutely clear if Applicants are limiting the koji mold or the processed koji mold. If Applicants intend for claims 6 and 7 to limit both of the alternative embodiments of 'koji mold' and 'processed koji' mold to wherein the molds are produced by the specific Aspergillus genus/species, it is suggested that the claims be reworded to read: 'wherein the koji mold or processed koji are molds belonging to the genus Aspergillus.' Note that this is merely one suggestion which could be implemented in order to overcome this rejection.

Claim 8 recites 'A set of a composition.' The Examiner cannot absolutely understand what Applicants mean by 'a set of a composition.' The recitation of 'a set of a composition' is confusing because it is unknown if Applicants mean to claim one

component of the composition (such as the ascorbic acid composition) apart from the koji mold? Clarification is necessary.

Claim 9 states ' A composition comprising 2-O-(ß-D glucopyranosyl) ascorbic acid…which is safe to the human body, for the set as defined in claim 8.' This claim is confusing because, first, claim 9 appears to depend upon claim 8 which is indefinite (and therefore claim 9 also possesses the indefinite matter from claim 8), but also appears to be in independent format. "for the set as defined in claim 8' (emphasis added) is not understood, and it cannot be ascertained if Applicants are claiming a composition comprising 2-O-(ß-D glucopyranosyl) ascorbic acid *alone* or if they are claiming a composition comprising 2-O-(ß-D glucopyranosyl) ascorbic acid and a koji mold or processed koji.

For these reasons, the ordinary artisan would have trouble ascertaining if they were infringing upon the Invention of claims 8 and 9; hence rendering the claims indefinite. It is noted that claims 8 and 9 were examined if they were directed toward the same subject matter as claim 1, that is, a composition comprising 2-O-(ß-D glucopyranosyl) ascorbic acid *and* a koji mold or processed koji.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hara et al. (JP 05013647 – full translation has been ordered) in view of Maeda et al. (WO 03/057707- as provided by Applicants' IDS of 5/6/2009) in light of Takeda et al. (US 2002/0031574 A1)*.

Hara et al. (JP 05013647) disclosed a Vitamin C rich fruit juice drink comprising fruit juice, kojic acid and ascorbic acid (see English abstract).

The phrase 'processed koji' is given its broadest interpretation within reason, consistent with the specification. The Specification does not provide any strict definition for the phrase 'processed koji,' but rather indicates that a 'processed koji' may be any crude extract or isolated compound from koji (koji mold). Kojic acid, found in the fruit juice drink composition of Hara et al. is a compound isolated from koji mold (a fermentation made with Aspergilli) according to Takeda et al. (US 2002/0031574 A1). Additionally, while Applicants do not explicitly state 'processed koji mold,' it appears, from the state of the art that 'koji' and 'koji mold' are the same and the terms 'koji' and 'koji mold' are used interchangeably to mean 'koji mold.' Applicants' Specification itself indicates that a 'processed koji' may be an extract from a koji mold ([0051]).

Hara et al. did not teach the incorporation of 2-O-(ß-D-glucopyranosyl) ascorbic acid.

2-O-(ß-D-glucopyranosyl) ascorbic acid was a known compound at the time the Invention was made according to Maeda et al. (WO 03/057707) who isolated this compound from Lycium fruits (Chinese wolfberry, of the Solanacea Family of plants)(see entire reference, especially p. 5 line 18- p. 6 line 8, Example 4, pp. 32-33 and page 1). Maeda et al. discovered that 2-O-(ß-D-glucopyranosyl) ascorbic acid had increased stability, an extended half-life and long-lasting activity and would be appropriate for using in foods and cosmetics (see p. 1). Maeda et al. noted that while vitamin C was a well-known therapeutic compound, providing effects such as anti-photo aging, anti-oxidant and UV damage prevention, vitamin C had "…extreme instability with respect to light, heat, oxygen and metal ions" (p. 2). Thus, Maeda et al. touted 2-O-(ß-D-glucopyranosyl) ascorbic acid as a more stable substitution for vitamin C; a 'pro vitamin c' (see entire reference, and p. 2).

One of ordinary skill in the art would have been motivated to substitute the ascorbic acid (vitamin C) for the provitamin C compound 2-O-(ß-D-glucopyranosyl) ascorbic acid as disclosed by Maeda et al. due to the superior stability of this provitamin C compound. Clearly, the ordinary artisan, having the above-cited references before him or her would have recognized the advantage of formulating a fruit juice formulation which had all of the antioxidant properties of ascorbic acid, yet was more stable and hence would provide antioxidant capabilities longer than ascorbic acid."[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

It is additionally noted that the phrase 'quasi-drug' and 'cosmetic' does not impart any structural limitations to the composition save for the fact that the prior art used to reject the claims must not be precluded from use as a 'quasi-drug' or 'cosmetic.' It is clear from the prior art references that the combination does not preclude the composition for use either as a cosmetic or 'quasi-drug.'

Claim 7 which states 'wherein the koji mold is a mold belonging to Aspergillus oryzae…' is broad enough to read on wherein the koji mold of the 'processed koji' is prepared by Aspergillus oryzae. The product of Hara et al.; kojic acid, is derived from koji. Thus, the 'processed koji' in the instant case, kojic acid, is a processed koji and kojic acid is the same compound independent upon its source or its method of manufacture. It is deemed that kojic acid may be prepared from any koji using any species of Aspergillus absent evidence to the contrary.

The Supreme court has acknowledged that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**…if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions…
>
> …**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

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Primary Examiner, Art Unit 1655
May 7, 2009